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MEDICATION SAFETY IN SECONDS

A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

Helping to achieve safe medication use

IDARUCIZUMAB (PRAXBIND®) AND IDARUBICIN (IDAMYCIN®): POSSIBLE LOOK-ALIKE NAME CONFUSION REPORTED BY ISMP

Submitted by: Veronica Fassio, Pharm.D., PGY-2 Medication Use Safety Resident

The Institute for Safe Medication Practices (ISMP) issued a warning on the potential risk to confuse idarucizumab (Praxbind®) with idarubicin (Idamycin®). Recently FDA -approved on 10/16/15, idarucizumab is an antidote for patients on dabigatran (Pradaxa®) who suffer a life-threatening bleeding event. The nonproprietary name idarucizumab shares the first five letters with the antineoplastic idarubicin. A hospital carrying both medications may be at risk for incorrect order entry from a computer system drop down menu or selection of the wrong medication from a storage location. A close call was reported to ISMP at a hospital where idarucizumab was incorrectly pulled from the stock, instead of idarubicin. Both medications were sitting alongside each other in the same refrigerator. Fortunately, a pharmacist noticed the error before the drug was administered. This incidence highlights a few considerations from the ISMP as well as suggestions for customizing these orderable items within the VA's computerized order entry system:

- Use mixed case (tallMAN) lettering for Pharmacy Orderable Items file (#50.7), for example: **IDA**rubicin and idaru**CIZUMAB**, (Figure 1);
- Consider adding a short descriptor (less than 74 characters) cautioning of Look-Alike/Sound-Alike potential in blue text (Display Restrictions/Guidelines) for idarubicin and idarucizumab (Figure 2);
- Consider adding a Quantity Dispensed message that contains a caution to confirm drug selection (Figure 2);
- Vials of idarubicin should not be stored near idarucizumab vials;

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NEWSWORTHY...

from the pbm

- Noxafil (Posaconazole): Dosing Errors When Switching Between Different Oral Formulations – 01/13/2016 - National PBM Bulletin

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VA PHARMACY BENEFITS MANAGEMENT SERVICES (PBM)

PBM maintains VA's national drug formulary, as well as promotes, optimizes, and assists VA practitioners with the safe and appropriate use of all medications.

VA CENTER FOR MEDICATION SAFETY (VA MedSAFE)

VA MedSAFE performs pharmacovigilance activities; tracks adverse drug events (ADEs) using spontaneous and integrated databases; enhances education and communication of ADEs to the field; and promotes medication safety on a national level.

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NEWSWORTHY...

from the fda

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FDA cautions about dosing errors when switching between different oral formulations of antifungal Noxafil (posaconazole); label changes approved

1/4/2016

Due to reports of dosing errors when switching between the two oral formulations of Noxafil (posaconazole), the patient information and outer carton have been revised to indicate that the oral formulations cannot be directly substituted for each other due to differences in how each formulation is dosed. FDA recommends that:

- *Prescribers should specify the dosage form, strength, and frequency on all prescriptions they write for Noxafil.*
- *Pharmacists should request clarification from prescribers when the dosage form, strength, or frequency is not specified.*
- Prescribers should follow the specific dosing instructions for each formulation.

Dosage for Noxafil Delayed-Release Tablets

Indication	Dose and Duration of Therapy
Prophylaxis of invasive *Aspergillus* and *Candida* infections	Loading Dose: 300 mg (three 100 mg delayed-release tablets) twice a day on the first day. Maintenance Dose: 300 mg (three 100 mg delayed-release tablets) once a day, starting on the second day. Duration of therapy is based on recovery from neutropenia or immunosuppression.

Dosage for Noxafil Oral Suspension

Indication	Dose and Duration of Therapy
Prophylaxis of invasive *Aspergillus* and *Candida* infections	200 mg (5 mL) three times a day. The duration of therapy is based on recovery from neutropenia or immunosuppression.
Oropharyngeal Candidiasis	Loading Dose: 100 mg (2.5 mL) twice a day on the first day. Maintenance Dose: 100 mg (2.5 mL) once a day for 13 days.
Oropharyngeal Candidiasis Refractory to Itraconazole and/or Fluconazole	400 mg (10 mL) twice a day. Duration of therapy should be based on the severity of the patient's underlying disease and clinical response.

Additional information can be found in the National PBM Bulletin issued last month.

Getting the most from our safety surveillance

USING THE VA ADVERSE DRUG EVENT REPORTING SYSTEM (VA ADERS) FOR FDA MEDWATCH REPORTING

Submitted by: Veronica Fassio, Pharm.D., PGY-2 Medication Use Safety Resident, Von Moore, Pharm.D., and Anthony Au, Pharm.D., BCPS

The VA Adverse Drug Event Reporting System (VA ADERS) staff recently conducted a national conference call on FDA MedWatch reporting using VA ADERS. The purpose of the presentation was to educate VA reporters on how to submit a "Grade A" FDA MedWatch report that provides essential information needed for the VA and FDA to determine associations between medical products and potential harm.

The FDA MedWatch is a voluntary reporting system for adverse events, quality issues, and use errors pertaining to medical products and devices. Adverse drug events (ADEs) are events where injury arises from the use of a drug as a result of an adverse drug reaction, drug-drug interactions, product quality problems, or drug overdoses.[1] Concerning ADEs, the purpose of FDA MedWatch is to gather case reports of these events in order to assess whether there is a signal for a medication to contribute a potential risk. If a signal is found, the FDA releases safety alerts and mandates actions (e.g. updating medication labels) in order to alert the public. Figure 1 provides an overview on what events and information to report to FDA MedWatch and VA ADERS.

Where does VA ADERS fit in the area of FDA MedWatch reporting? VA ADERS is the national reporting system for the

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VA. All observed ADEs should be submitted to VA ADERS as these reports are important for internal VA patient safety initiatives. *[NOTE: This is typically done by designated pharmacists via a web-based system. Providers should continue to enter allergies and adverse reactions into the designated field in CPRS as these entries are used as a basis for VA ADERS reporting and for patient safety via drug-allergy order checks]*. In addition to reporting these events to VA ADERS, the reporter is given the option to submit reports directly to FDA by completing an electronic MedWatch report through VA ADERS. Once complete, the reporter finalizes the submission using VA ADERS fax utility to fax the report to the FDA. Below are a few considerations when preparing a report.

- Complete sections as thoroughly as possible.
- Include baseline information and progression during and after the event.
- Include time courses for pertinent health conditions and medications.

In summary, the details in a FDA MedWatch report can support the VA and FDA in promoting the safe use of medications through communications, education, and other medication use safety initiatives. When preparing a report, reporters should consider if the information provided is adequate & useful for the VA and FDA in determining the significance of a medication's effect on patients. For training resources pertaining to ADE reporting using VA ADERS (Training Video and Slides), VA pharmacists, pharmacy residents, pharmacy technicians and all other disciplines should visit the VHA MedSafe Portal's Training Materials at https://vaww.cmop.med.va.gov/MedSafe_Portal/.

REFERENCE:
Veterans Health Administration, Department of Veterans Affairs. VHA Directive 2014-1070: Adverse drug event reporting and monitoring. http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=3043 (accessed 2016 Feb 19).

Figure 1: FDA MedWatch Reporting Using VA ADERS

Information Needed
Sufficient details on the timing & presentation of ADE
Complete knowledge of drugs involved and their formulations
Clear understanding of potential confounders (i.e. other medications or comorbidities)

*An unexpected presentation of abnormal labs, such as an increase in serum creatinine or liver function tests, should be reported to FDA MedWatch. Additionally, a therapeutic failure to a product (e.g. experiencing a stroke while on warfarin) should be reported as well.

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(continued from page 1)

- Add auxiliary labels to idarucizumab and/or idarubicin containers to alert staff who may access the drug;
- Inform staff about the difference between idarubicin and idarucizumab.

REFERENCE:
Institute for Safe Medication Practices. Warning: Don't confuse idarucizumab with IDArubicin. *ISMP Medication Safety Alert! Acute Care*. 20(22): 1,5. November 5, 2015. ■

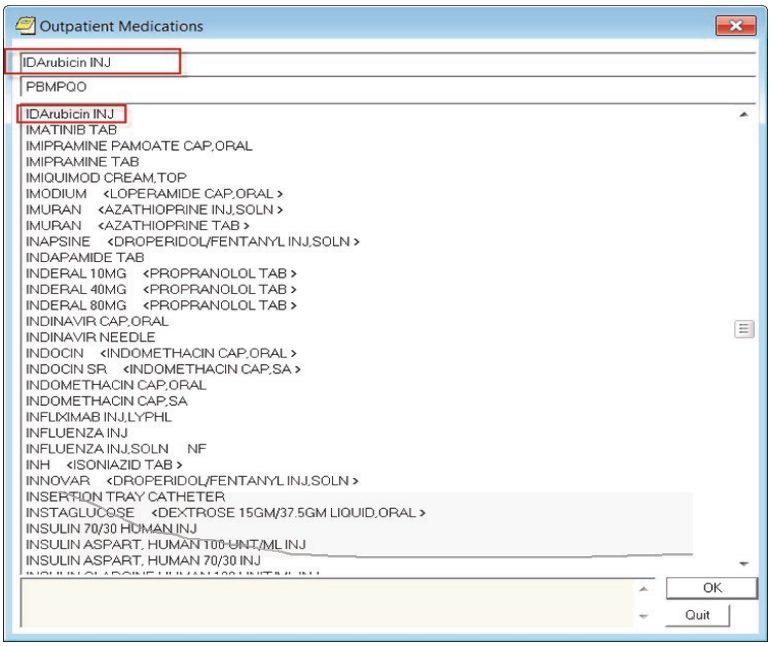

Figure 1. (Left) Mixed case (tallMAN) lettering for idarubicin helps to prevent LA/SA confusion between idarucizumab and idarubicin while ordering in the computerized provider order entry system.

Figure 2. (Below) Blue text (Display Restrictions/Guidelines) at the top of the order screen alerts providers about possible LA/SA confusion between idarucizumab and idarubicin, while a second message in the "Quantity Dispensed" section in the middle of the order screen reiterates the caution.